In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-897V
Filed: December 6, 2022
PUBLISHED

TIMOTHY WOODS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Finding of Fact; influenza (flu) vaccine; optic neuritis; diagnosis.

Mark Theodore Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for petitioner.
Mary Eileen Holmes, U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACT[1]

On June 30, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012)[2], alleging that as a result of an influenza ("flu") vaccination he received on October 11, 2014, he suffered orbital eye pain, decreased vision, vision loss, and optic neuritis. (ECF No. 1.) Alternatively, petitioner alleges the subject flu vaccination significantly aggravated these conditions. (*Id.*)

Respondent recommended that compensation be denied, arguing, *inter alia*, that there is not preponderant evidence to support a finding that petitioner's symptoms are due to optic neuritis. (ECF No. 14, p. 6.) On March 30, 2021, a fact hearing was held

[1] Because this document contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

regarding the diagnosis issue in this case. For the reasons described below, I now find that petitioner has not preponderantly established that he suffered optic neuritis.

I. Procedural History

This case was initially assigned to Special Master Millman. (ECF No. 4.) Petitioner filed medical records in support of his claim on July 7, 2017, and an affidavit on October 26, 2017. (ECF Nos. 6, 9.) After reviewing petitioner's materials, respondent filed his Rule 4(c) report contesting entitlement on March 16, 2018. (ECF No. 14.) Respondent argued, *inter alia*, that petitioner failed to establish that his symptoms were caused by optic neuritis. (*Id.* at 6.)

In response to respondent's Rule 4(c) report recommending against compensation, petitioner filed a report from neuroimmunologist Lawrence Steinman, M.D., on June 29, 2018. (ECF No. 18; Ex. 8.) On November 30, 2018, respondent filed a responsive report from neuro-ophthalmologist Marc A. Bouffard, M.D. (ECF No. 21; Ex. A.) Respondent also filed a responsive report from immunologist J. Lindsay Whitton, M.D., Ph.D., on December 13, 2017. (ECF No. 23; Ex. C.) Petitioner then filed a supplemental report from Dr. Steinman on February 22, 2019. (ECF No. 28; Ex. 36.) On April 3, 2019, respondent filed supplemental reports from Dr. Bouffard and Dr. Whitton. (ECF Nos. 34, 35; Exs. G, H.)

The case was subsequently reassigned to my docket on June 6, 2019. (ECF No. 37.) At the request of petitioner, I held a Rule 5 conference with the parties on October 8, 2019. (ECF No. 39.) During the conference, I noted that both of respondent's experts, Drs. Bouffard and Whitton, highlighted a statement from petitioner's neuro-ophthalmologist Matthew Thurtell, M.D, in which he stated, "Based on the history, I suspect [petitioner] had an attack of optic neuritis." (*Id.* at 1 (citing Ex. A, p. 3; Ex. C, p. 3).) Although Dr. Whitton stressed that Dr. Thurtell's phrasing did not constitute a diagnosis, I did not find it accurate to assert that a diagnosis was not made. (*Id.*) However, I cautioned that this "does not mean that the basis for diagnosis is beyond challenge[.]" (*Id.* at 1-2.) I further noted petitioner's nine-month delay in seeking treatment makes it more difficult "to assess . . . the nature of petitioner's optical condition." (*Id.* at 2.) Given the sparse factual record in this case and that petitioner's condition appears to be relatively mild, I encouraged the parties to explore litigative risk settlement and recommended that if the parties wished to continue litigation that petitioner seek a report from a neuro-ophthalmologist to provide a more in-depth rebuttal to Dr. Bouffard and/or undergo neuroimaging. (*Id.* at 3.)

On December 10, 2019, respondent filed a status report indicating that he was not interested in settlement negotiations and intended to continue defending the case. (ECF No. 41.) Thereafter, on August 7, 2020, petitioner submitted an expert report from ophthalmologist Todd Allen Lefkowitz, M.D. (ECF No. 54; Ex. 40.) On the same date, petitioner filed a status report indicating that he decided not to undergo neuroimaging. (ECF No. 55.) On October 19, 2020, respondent submitted a supplemental report from Dr. Bouffard responding to Dr. Lefkowitz. (ECF No. 59; Ex. J.) Petitioner subsequently

filed a status report requesting that the case be scheduled for an entitlement hearing. (ECF No. 60.)

I held a status conference with the parties on December 4, 2020. (ECF No. 61.) I advised that "it may be reasonable to first resolve on the written record the question of whether there is preponderant evidence that petitioner suffered optic neuritis" before proceeding to an entitlement hearing. (*Id.*) However, I noted that "petitioner may wish to have an opportunity to testify himself and so a more limited fact hearing may also be appropriate before proceeding to such a fact finding." (*Id.*) I added that "following the fact hearing, the parties would be permitted to consult with their experts to determine whether they wish to submit supplemental expert reports before resolving the question of diagnosis on the written record." (*Id.* at n.1.) Shortly thereafter, the parties confirmed availability for a fact hearing in March 2021. (ECF No. 62.)

On January 19, 2021, I issued a prehearing order setting a video fact hearing for March 30, 2021, wherein I indicated that prehearing submissions were not required but that the parties could file a joint submission clarifying any issues if they wished. (ECF No. 63.) Respondent then filed an individual prehearing submission on March 23, 2021, arguing for the dismissal of petitioner's case. (ECF No. 64.) On the same date, petitioner moved to strike respondent's prehearing submission because it was not jointly filed as described in the prehearing order. (ECF No. 67.) Respondent filed his response to petitioner's motion on March 29, 2021 (ECF No. 68), and petitioner filed his reply on the same date (ECF No. 69). In his response, respondent deferred to the court's discretion regarding petitioner's motion to strike. (*Id.*) However, he emphasized his desire to preserve his argument for appeal that he should have been permitted to present testimony from his expert, Dr. Bouffard, because the fact hearing was intended to focus on the question of diagnosis. (*Id.*) Respondent indicated that "he was amenable when the court proposed a fact hearing on the issue of diagnosis" but represented that he "was not aware that expert testimony on the issue of diagnosis would not be heard." (*Id.* at 2.)

I issued an order granting petitioner's motion to strike on March 29, 2021. (ECF No. 70.) I noted that although the "fact hearing is prompted by the idea of resolving diagnosis as a threshold question as respondent suggests, the purpose of the hearing is only to elicit the fact testimony petitioner may additionally wish to have considered." (*Id.* at 2.) I stressed that the prior order proposing the fact hearing explicitly stated that the fact hearing would not constitute the close of the evidentiary record regarding diagnosis and that the parties would be permitted to continue the exchange of expert reports before resolving petitioner's diagnosis on the written record. (*Id.* (citing ECF No. 61, n.1).) I concluded that respondent's request to elicit testimony from Dr. Bouffard was premature and indicated that if respondent still felt expert testimony was necessary to resolve the issue of diagnosis following the opportunity to submit supplemental expert reports, respondent should raise such an argument at that time. (*Id.*)

A fact hearing was held on March 30, 2021, at which petitioner and his wife, Tonya Woods, testified. (ECF No. 73 (Transcript of Proceedings ("Tr.")).) Following the

hearing, petitioner filed outstanding medical and employment records identified during the hearing and a statement of completion. (See ECF Nos. 71, 74, 81-83.) The parties subsequently conferred regarding the need for supplemental reports. (ECF No. 84.) Respondent expressed interest in filing a supplemental report, and petitioner indicated his desire to reserve the right to file a supplemental report following the submission of respondent's expert report. (*Id.*) On October 15, 2021, respondent filed a supplemental report from Dr. Bouffard. (ECF No. 86; Ex. L.) Petitioner requested a status conference to determine next steps in the case. (ECF No. 87.)

On March 1, 2022, I held a status conference with the parties. (ECF No. 88.) I shared my view that the factual record had been sufficiently developed to fairly resolve the issue of diagnosis. (*Id.* at 1.) I also indicated that my preliminary view that entitlement in this case should also be resolved on the written record pursuant to Vaccine Rule 8(d). (*Id.*) The parties provided input on whether the case should proceed directly to a comprehensive resolution of entitlement or whether it would be appropriate to first issue a fact finding regarding the issue of diagnosis. (*Id.*) Respondent expressed a preference for first issuing a finding of fact regarding diagnosis and noted that he would not revisit his settlement posture without guidance on the threshold issue. (*Id.*) Conversely, petitioner indicated a preference for proceeding to resolution of entitlement pursuant to Vaccine Rule 8(d). (*Id.*) Petitioner expressed concern that issuance of a finding of fact would not guarantee productive settlement discussions and could delay resolution of the case. (*Id.*) However, on March 30, 2022, the parties filed a joint status report indicating that petitioner was open to either proposed course of action. (ECF No. 89.) Respondent reiterated his preference for a briefed finding of fact on diagnosis. (*Id.*)

The parties filed simultaneous briefs regarding the factual issue of diagnosis on July 1, 2022. (ECF Nos. 92, 93.) Concurrent with his initial brief, petitioner filed a medical article examining optic disc cupping following optic neuritis. (ECF No. 91; G. Rebolleda et al., *Optic Disc Cupping After Optic Neuritis Evaluated with Optic Coherence Tomography*, 23 EYE 890 (Ex. 47).) On September 2, 2022, the parties submitted concurrent responsive briefs. (ECF Nos. 95, 97.) Contemporaneous with his responsive brief, respondent submitted a supplemental expert report from Dr. Bouffard. (ECF No. 96; Ex. M.)

Petitioner moved to strike respondent's responsive brief and Dr. Bouffard's supplemental expert report on September 2, 2022. (ECF No. 98.) On September 7, 2022, respondent filed a response to petitioner's motion and a cross-motion to strike the Rebolleda et al. medical article that was newly filed with petitioner's initial brief. (ECF No. 99.) Petitioner filed his reply on September 7, 2022. (ECF No. 100.)

This matter is now ripe for a finding of fact regarding the issue of diagnosis as well as a ruling on the parties' competing motions to strike the additional evidence filed with their respective briefs.

II. Factual History

a. As Reflected in Medical Records

Petitioner was thirty-six years old when he received the flu vaccine on October 11, 2014. (Ex. 4, p. 1.) He received the flu vaccine at UnityPoint Health Jones Regional Medical Center, where he worked as a respiratory therapist. (*Id.*) Petitioner's pre-vaccination medical history is significant for depression, seasonal affective disorder, stress, cigarette smoking, respiratory infections, and gastroesophageal reflux disease. (*See*, *e.g.*, Ex. 1., p. 1; Ex. 2, pp. 19-21, 28-29; Ex. 3, pp. 9, 14.) Although petitioner wore glasses for myopia (nearsightedness) prior to vaccination, he did not appear to have any significant preexisting eye problems. (*See* Ex. 44, p. 7 (routine eye examination on October 3, 2012); *see also* Ex. 3, p. 9 (Dr. Thurtell noting petitioner's history of myopia).

Nearly nine months after vaccination, on June 29, 2015, petitioner sought care from optometrist Bryan Hoke, O.D. (Ex. 44, p. 5.) Petitioner reported a nine-month history of headaches, blurry vision and decreased color vision in the left eye, and pain in his left eye and left temple. (*Id.*) Petitioner's eye examination was normal. (*Id.*) Dr. Hoke referred petitioner to the Wolfe Eye Clinic for further evaluation. (*Id.* at 5, 2.)

On July 6, 2015, petitioner presented to ophthalmologist LeAnn Larson, M.D., at the Wolfe Eye Clinic with complaints of poor color vision, difficulty seeing at night, left orbital pain, and left eye pain. (Ex. 1, p. 1.) Petitioner reported difficulty seeing red and green from his left eye as well as sinus pressure with radiation to the left temple area and the left side of his neck. (*Id.*) Petitioner described periorbital and temporal pain. (*Id.*) Dr. Larson indicated that petitioner had localized discomfort and could "create some discomfort if he presses in the middle of his brow" or "over the left nasal aspect of his nose." (*Id.*) Petitioner also reported that "his blood pressure gets high at times." (*Id.*) Dr. Larson noted that petitioner's symptoms began after receiving the flu vaccine nine months prior. (*Id.*) She further noted that nine months prior, petitioner experienced left eye pain for about one day, after which petitioner's "vision seemed to decrease for about a month." (*Id.*) After that point, petitioner reported that his vision remained largely the same. (*Id.*) However, he explained that his vision would become blurry when he got angry or when he mowed the lawn. (*Id.*) He also described an episode of eye pain "[t]hat lasted a couple of days a couple of weeks ago." (*Id.*) Petitioner shared his concern that he may have optic neuritis based on his own internet research. (*Id.*)

During the visit, Dr. Larson performed a comprehensive eye examination. Dr. Larson found that petitioner's vision was "excellent," measuring 20/20 in the right eye and 20/25 in the left eye. (Ex. 1, pp. 1-2.) The Ishihara Test, which measures color vision, revealed normal color vision in both of petitioner's eyes with petitioner correctly identifying all color plates used in the test. (*Id.* at 2.) Dr. Larson noted that petitioner's pupils were "[e]qual, round, and normally reactive" and did not show evidence of Relative Afferent Pupillary Defect ("RAPD"). (*Id.*) Petitioner's intraocular pressure in both eyes was normal. (*Id.*) However, Dr. Larson observed that the optic nerve fiber

layer in petitioner's left eye was thinning, which she noted was "more prominent temporally." (*Id.* at 1.) She also documented granular changes in both eyes and "poorly defined macular reflexes" in petitioner's left eye. (*Id.* at 2.) Dr. Larson assessed petitioner as having insignificant cataracts due to minor peripheral lens opacities, granular changes in the macula, and retinal pigment epithelium changes. (*Id.*) She recommended petitioner receive a neuro-ophthalmology consult. The next day, on July 7, 2015, petitioner called Dr. Larson's office to add that "[he] did not mention that he has a sinus infection and is thinking that this has been chronic for 9 months." (*Id.* at 11.)

Over the next few months, petitioner saw his primary care physician, Charles Vernon, for complaints unrelated to his vision problems. On August 4, 2015, petitioner visited Dr. Vernon for a spot on the back of his throat. (Ex. 2, p. 14.) The review of systems for this visit was positive for subjective visual disturbances, and Dr. Vernon noted that petitioner had seen an ophthalmologist. (*Id.* at 16.) The next month, on September 29, 2015, petitioner returned to Dr. Vernon for an upper respiratory tract infection. (*Id.* at 9-10.) Petitioner reported that he resumed smoking about a pack of cigarettes per day about eight or nine months prior when his wife had a stroke. (*Id.* at 11.) He also reported being under increased stress due to his wife's health issues and nursing school responsibilities and requested "something to help him with the stress." (*Id.* at 11-12.) On October 28, 2015, petitioner again visited Dr. Vernon for his chronic allergic rhinitis. (*Id.* at 5.) At this visit, Dr. Vernon was primarily concerned about petitioner's stress level and cigarette smoking. (*Id.* at 5-6.) Under review of systems, Dr. Vernon noted that petitioner was scheduled for a neuro-ophthalmology consult "to evaluate for the possibility of an optic neuritis disorder." (*Id.* at 8.)

On November 4, 2015, several months after petitioner's ophthalmology visit with Dr. Larson, petitioner saw neuro-ophthalmologist Matthew Thurtell, M.D. (Ex. 3, p. 9.) Petitioner reported that after receiving the flu vaccine one year earlier, he experienced a headache about one or two days after the shot, followed by progressively worsening ability to see color and cloudy vision "over days." (*Id.*) Petitioner explained that these symptoms lasted for about five months before they improved to the point where it was not "as noticeable." (*Id.*) He described flares of decreased vision associated with exercise and frustration. (*Id.*) He also reported experiencing left orbital and temple pain similar to the headache he had after the flu shot a couple of times a week. (*Id.*) Dr. Thurtell noted that petitioner's description of symptoms was consistent with "a classic Uhthoff phenomenon" in his left eye. (*Id.* at 14.) He also documented petitioner's history of smoking cigarettes. (*Id.* at 10.) Upon examination, petitioner's vision measured 20/20 in both eyes. (*Id.* at 11, 14.) Additionally, petitioner again correctly identified all fourteen color plates used in the Ishihara Test, though he informed Dr. Thurtell that "it is more difficult to read the color plates" in his left eye. (*Id.*) Petitioner's examination revealed no evidence of APD. (*Id.*) Dr. Thurtell noted that petitioner's left eye had a "[s]luggish" pupil response (*id.* at 11), but in another note from the same visit recorded that his pupils were "briskly reactive" without evidence of RAPD (*id.* at 14). He also observed "mild temporal rim pallor" in petitioner's left disc. (*Id.* at 12.)

While at Dr. Thurtell's office, petitioner underwent an Optical Coherence Tomography ("OCT") scan of the optic nerves, which revealed inferotemporal retinal nerve fiber layer ("RNFL") thinning and diffuse ganglion cell layer ("GCL") thinning in petitioner's left eye. (Ex. 3, pp. 13, 14.) Dr. Thurtell noted that petitioner's "neuro-ophthalmic evaluation showed findings consistent with a mild optic neuropathy" in the left eye." (*Id.* at 14.) He stated, "Based on the history, I suspect [petitioner] had an attack of optic neuritis [in the left eye]." (*Id.*) He further noted that "[t]he attack began shortly after a flu vaccine and, thus, the attack may have been vaccination-related." (*Id.*) Dr. Thurtell specifically added "[o]ptic neuritis, left" to petitioner's active problem list and included "[o]ptic neuritis, left" in the assessment section of the encounter with accompanying ICD billing codes. (*Id.* at 10, 13.) He recommended a brain MRI with contrast "to evaluate for underlying demyelinating disease," but petitioner indicated that he preferred not to pursue a brain MRI because he was not experiencing other neurological symptoms at that time. (*Id.* at 14.)

Petitioner returned to Dr. Vernon on January 27, 2016. (Ex. 2, p. 2.) During the visit, petitioner requested Dr. Vernon sign a release for him to abstain from future flu vaccines due to petitioner's concern that the flu vaccine caused his attack of optic neuritis. (*Id.* at 4.) Dr. Vernon noted that it was a "reasonable request" but believed there were other factors that could have contributed to petitioner's condition. (*Id.*) Dr. Vernon opined that petitioner's cigarette use was "probably a more common cause of optic neuritis" and noted that petitioner's blood pressure was slightly elevated. (*Id.*)

Over a year later, on March 30, 2017, petitioner presented to Peterson Eye Care. (Ex. 6, p. 1.) Petitioner's eye examination indicated normal vision, with both eyes measuring 20/20. (*Id.*) The one-page handwritten record appears to recommend petitioner follow up with a neuro-ophthalmologist for optic neuritis. (*Id.*)

On December 1, 2017, petitioner followed up with Dr. Larson at the Wolfe Eye Clinic for ongoing intermittent left eye pain. (Ex. 42, p. 1.) Petitioner reported episodes of blurry vision and difficulty seeing colors. (*Id.* at 1-2.) Dr. Larson performed an OCT scan, which showed cup-to-disc asymmetry with both eyes being thin but the left eye thinner than the right. (*Id.* at 2.) She recommended petitioner follow up with neuro-ophthalmology. (*Id.*)

Petitioner did not return to the Wolfe Eye Clinic until February 18, 2020, when he saw Cory Bower, O.D. (Ex. 42, p. 4.) Petitioner reported that his vision in his left eye remained "slightly dim" but denied any pain. (*Id.*) Petitioner underwent another OCT scan, which again showed abnormal RNFL inferotemporal thinning in his left eye. (*Id.* at 5.) Dr. Bower noted that this finding is consistent with optic neuritis. (*Id.*) He concluded that petitioner's condition was "stable" and "[i]nsignificant" in terms of overall severity. (*Id.* at 5, 6.)

Petitioner did not submit any medical records relevant to his condition beyond February 18, 2020.

b. As Reflected in Petitioner's Affidavit

Petitioner filed an affidavit on October 26, 2017. (Ex. 7.) He averred that prior to receiving the flu vaccine on October 11, 2014, he was in good health. (*Id.* at 1.) At the time of vaccination, petitioner was working full-time as a respiratory therapist and attending nursing school as an evening student. (*Id.*) He received the flu vaccine because it was required by his employer. (*Id.*) He attested that after receiving the flu vaccine, he started to feel pain around his eyes and in his forehead. (*Id.*) Additionally, it became difficult for him to see at night while driving and to differentiate between red and green colors. (*Id.*) Petitioner averred that these symptoms began "in October 2014." (*Id.* at 2.)

Although petitioner attested that the onset of his symptoms began in October 2014, he explained that he delayed seeking treatment for several reasons.[3] (*Id.*) Petitioner explained that his wife unexpectedly had a stroke on January 1, 2015, "which left her hospitalized for a long period of time and suffering from permanent effects." (*Id.*) He averred that prior to her stroke, his wife was the primary caregiver of their children and "took care of all aspects involving [their] household." (*Id.*) Following his wife's stroke, petitioner attested that he became the primary caregiver for his wife and children. (*Id.*) Additionally, petitioner stated that he took a leave of absence from his job as a respiratory therapist to care for his family. (*Id.*)

Petitioner explained that once he returned to work at the Jones Regional Medical Center, he "informally consulted about [his] symptoms with doctors and nurses." (*Id.*) Petitioner stated that he "saw no need to make a formal appointment with a specialist" because he "informally interacted and consulted with doctors and nurses about [his] symptoms on a frequent basis." (*Id.*) He also noted that his symptoms did not get worse during the winter of 2014 and spring of 2015. (*Id.*) Given that his symptoms "remained relatively constant," he did not feel inclined to see a specialist. (*Id.*) Petitioner stated that when his symptoms progressed in June 2015 and his personal life "had stabilized," he made time to visit an eye specialist. (*Id.*)

c. As Reflected in Testimony

Petitioner testified prior to receiving the flu vaccine on October 11, 2014, he was in good health, though he got bronchitis once a year and started wearing prescription glasses in his twenties. (Tr. 34.) He testified that he received the flu vaccine because both his employer and his nursing program recommended that healthcare providers receive the flu vaccine to protect patients. (*Id.* at 9.) After receiving the flu vaccine, petitioner testified that he did not remember any initial side effects. (*Id.* at 10.) He recalled that "a week or two" after receiving the vaccine, he had difficulty seeing green while attending a sporting event. (*Id.*) He described his color vision in his left eye as "disintegrating." (*Id.*) After that point, he began having difficulty seeing red. (Tr. 10.)

[3] Petitioner averred that he did not seek treatment for his vision problems until July 6, 2015, when he saw Dr. Larson. (Ex. 7, p. 2.) However, the medical records indicate that he first visited Dr. Hoke with complaints of blurry vision and difficulty seeing colors on June 29, 2015. (Ex. 44, p. 5.)

Following the issues with color vision, petitioner testified that he began experiencing orbital pain around his left eye and episodes where it felt like he was opening his eye underwater.[4] (*Id.* at 11.)

Although petitioner did not seek treatment for several months after he first noticed symptoms, he recalled speaking with his wife and nurses and doctors at the Jones Regional Medical Center about his vision problems. (Tr. 11.) Petitioner stated that his coworkers advised him to "get seen outside of the facility." (*Id.* at 12.) Petitioner testified that he delayed seeking treatment for his eye problems for several reasons, including his fear that something was "seriously wrong" and his competing work and school responsibilities. (*Id.* at 13.) However, he averred that the primary reason he delayed treatment was due to his wife's stroke on January 1, 2015. (*Id.*) Petitioner testified that the stroke left his wife with several physical disabilities, requiring him to become the primary caretaker for his wife and their two children. (*Id.* at 16, 18.) Prior to her stroke, petitioner's wife took care of their two children and performed household chores. (Tr. 14, 18.) Petitioner testified that following his wife's stroke, he took six to eight weeks of leave from work and briefly delayed returning to nursing school for the spring 2015 semester. (*Id.* at 17-18; 40-41, 50.) He testified that he returned to school by the end of January and resumed work in either February or March 2015. (*Id.* at 17-18, 50.)

During this time, petitioner was more focused on his wife and household responsibilities than on his vision issues. (Tr. 19.) He stated that his orbital pain was not constant, though at times it was severe, and he periodically experienced sudden bouts of cloudy vision "depending on [his] stress level." (*Id.*) His color vision remained the same. (*Id.*)

Petitioner testified that after he finished his nursing program at Kirkwood Community College in mid-May 2015, he made an appointment to address his eye problems. (Tr. 21.) He recalled seeing an optometrist in June 2015 and getting a referral to the Wolfe Eye Clinic. (*Id.* at 21-22.) When petitioner first saw Dr. Larson at the Wolfe Eye Clinic, he recalled being "scared" after Dr. Larson's "demeanor changed" during his eye examination. (*Id.* at 22.) He testified that Dr. Larson told him that he could have optic neuritis, though she was unsure, and that he needed to see a neuro-ophthalmologist to obtain a diagnosis. (*Id.* at 23.) Petitioner explained that he then had to wait for an available appointment with a neuro-ophthalmologist at another facility. (*Id.* at 26.)

During petitioner's appointment with Dr. Thurtell in November 2015, petitioner recalled Dr. Thurtell advising him that he had optic neuritis and that "in his experience, the influenza vaccine could be linked to this." (Tr. 26; *see also id.* at 58.)

At the time of the hearing, petitioner testified that he did not recall the last time he experienced eye pain or blurry vision and that his color vision had improved

[4] Petitioner later distinguished his orbital pain from sinus pressure associated with the sinus infection he was experiencing at the time of his visit to Dr. Larson on July 6, 2015. (Tr. 57.)

significantly, though he still struggled with red and green colors appearing dull. (Tr. 27.) He further testified that his right eye "does a really good job compensating for [his] left eye." (*Id.*) Petitioner stated that he was a current smoker at the time of the hearing. (*Id.* at 55.) Additionally, he testified that he was diagnosed with high blood pressure and that he takes hydrochlorothiazide, a blood pressure medication. (*Id.* at 38.)

Petitioner's wife, Tonya Woods, also provided testimony. (Tr. 60-67.) Ms. Woods's understanding is that petitioner was diagnosed with optic neuritis. (*Id.* at 61.) She recalled petitioner having trouble seeing colors and experiencing eye pain "once in a while" after receiving the flu vaccine in October 2014. (*Id.*) She noted that petitioner typically avoids dealing with health concerns and stress. (*Id.* at 62.) She testified that she "couldn't do anything" after her stroke in 2015 and that petitioner had to take over all household and childcare responsibilities. (*Id.* at 64, 67.)

III. Expert Opinions[5]

a. Petitioner's Experts

i. Lawrence Steinman, M.D.

In support of his claim, petitioner presented an expert opinion by neuroimmunologist Lawrence Steinman, M.D. Dr. Steinman received his medical degree from Harvard in 1973. (Ex. 9, p. 1.) He is board-certified in neurology and has practiced adult and pediatric neurology at Stanford University. (*Id.* at 2; Ex. 8, p. 1.) Dr. Steinman has treated patients, both adults and children, who suffered from various forms of inflammatory neuropathy, including transverse myelitis, acute disseminated encephalomyelitis, neuromyelitis optica, multiple sclerosis, and others. (Ex. 8, p. 1.) He is currently a professor of neurology at Stanford University. (*Id.*; Ex. 9, p. 1.) Dr. Steinman's research focuses on how the immune system attacks the nervous system, and he has published on various topics involving vaccines and neurological disorders, including molecular mimicry. (Ex. 8, p. 1; Ex. 9, pp. 5-46.) He holds numerous American and European patents, including several U.S. patents relating to vaccines. (Ex. 8, p. 3; Ex. 9, pp. 2-3.)

The bulk of Dr. Steinman's expert reports focused on the mechanism of causation. (*See generally* Ex. 8; Ex. 36.) Dr. Steinman only briefly discussed the diagnosis dispute in his first supplemental report. In response to Dr. Bouffard's opinion on diagnosis, Dr. Steinman stressed that "Dr. Bouffard opines from a different context than that of the treating physicians." (Ex. 36, p. 1.) Dr. Steinman deferred to the diagnosis made by Dr. Thurtell, the "boots on the ground" treating neuro-ophthalmologist. (*Id.*)

[5] The expert reports offered by the parties discussed issues beyond the diagnosis dispute. For purposes of this fact finding, only aspects of the expert reports related to diagnosis are discussed.

ii. Todd A. Lefkowitz, M.D.

Petitioner also presented an expert report from board-certified ophthalmologist Dr. Lefkowitz. (Ex. 40.) Dr. Lefkowitz received his medical degree from New York University School of Medicine in 1977 and completed an ophthalmology residency at Georgetown University in 1981. (*Id.* at 1; Ex. 41, pp. 1-2.) He has practiced ophthalmology since 1981 and received his board certification in 1982. (Ex. 40, p. 1; Ex. 41, p. 1.) He currently practices as an ophthalmologist at Walman Eye Center as well as an ophthalmology hospitalist and trauma specialist at Banner Hospitals in Arizona. (Ex. 41, p. 1.) He also serves as a clinical assistant professor at the University of Arizona Medical School. (*Id.*) He performs various types of eye surgeries, including LASIK and cataract surgeries. (Ex. 40, p. 1.) Dr. Lefkowitz did not discuss any experience in neuro-ophthalmology in his expert report or curriculum vitae. (*See generally* Ex. 40; Ex. 41.)

In response to Dr. Bouffard's report proposing alternative etiologies for petitioner's symptoms, Dr. Lefkowitz asserted that petitioner did not suffer from ischemic, post-inflammatory, glaucomatous, or toxic etiologies. (Ex. 40, p. 3.) He explained that these etiologies present with accompanying signs. (*Id.*) Glaucoma presents with high intraocular pressure and distinctive visual field defects, post-inflammatory processes present with peri-orbital pain, ischemic etiologies present with cardiovascular disease, and toxic etiologies are accompanied by exposure to toxic substances. (*Id.*) Regarding glaucoma, he concluded that petitioner's visual testing did not suggest glaucoma. (*Id.*) He concluded that petitioner did not suffer from any other alternative etiology other than optic neuritis without further explanation. (*Id.*) He did not address any of Dr. Bouffard's specific concerns about petitioner's presentation being inconsistent with optic neuritis. (*See id.*)

b. Respondent's Experts

i. Marc A. Bouffard, M.D.[6]

Respondent offered an expert opinion from Dr. Bouffard, a neurologist who specializes in neuro-ophthalmology. Dr. Bouffard received his medical degree from Tufts University School of Medicine in 2012. (Ex. B, p. 2.) He then completed a neurology residency at Beth Israel Deaconess Medical Center, a neuro-ophthalmology fellowship at the Massachusetts Eye and Ear Infirmary, and a fellowship in Advanced General and Autoimmune Neurology at the Massachusetts General Hospital. (*Id.*; Ex. A, p. 2.) He currently practices at the Beth Israel Deaconess Medical Center where he routinely sees patients with optic neuritis. (Ex. A, p. 2.) He has written multiple peer-reviewed publications in the field of neuro-ophthalmology, including two articles on neuroimaging modalities in neuro-ophthalmic disease. (*Id.*; Ex. B, pp. 2-3.)

[6] As discussed in a later section, Dr. Bouffard's supplemental expert report filed as Exhibit M is not being considered. Therefore, this report is not discussed.

As an initial matter, Dr. Bouffard explained the difference between optic neuropathy and optic neuritis. (Ex. A, p. 4.) He indicated that optic neuropathy refers broadly to optic nerve dysfunction, while optic neuritis refers specifically to "immune-mediated inflammation of the optic nerve." (*Id.*) He suggested that optic nerve damage can be caused by several different processes, including but not limited to inflammatory disorders such as optic neuritis. (*Id.*)

Regarding the typical clinical course for optic neuritis, Dr. Bouffard noted that "its presenting features are well defined." (Ex. A, p. 5.) According to Dr. Bouffard, individuals suffering from optic neuritis usually suffer pain "centered on and around the globe" that is exacerbated with eye movements. (*Id.* at 4.) He explained that optic neuritis patients typically experience pain "up to a few days" before vision loss occurs and resolves "within a few days of the onset of vision loss." (*Id.*) He opined that pain lasting longer than seven days after vision loss "should raise suspicion for alternate diagnoses." (*Id.*)

To provide further guidance on the clinical features of optic neuritis, Dr. Bouffard discussed the optic neuritis treatment trial ("ONTT"), which examined 457 patients from 1988 to 1991. (Ex. A, p. 5.) The ONTT demonstrated that "visual recovery began within a month of the initial attack" and that "[p]ain is typically present for under a week, resolving more rapidly than vision loss." (*Id.*) Dr. Bouffard opined that ongoing inflammation is "extremely rare," and that most individuals experience "discrete attacks." (*Id.*) He further noted that "subtle functional abnormalities of the optic nerve" may continue after recovery from optic neuritis. (*Id.*) Specifically, individuals who recover from optic neuritis may continue to experience "[s]ubtle defects of color vision and contrast sensitivity." (*Id.*) Additionally, patients may have "[e]pisodic visual deterioration" associated with elevated body temperature, known as Uthoff's phenomenon. (Ex. A, pp. 5-6.) Dr. Bouffard emphasized that "Uthoff's phenomenon is painless, provoked by high temperature, transient, and not specific to demyelinating optic neuritis." (*Id.* at 6 (emphasis removed).) He also suggested that patients who recover from optic neuritis typically have mild atrophy of the nerve that may be shown by RNFL measurements or OCT studies. (*Id.*)

Although Dr. Bouffard agreed that petitioner "clearly has a mild optic neuropathy affecting the left eye," he cautioned that a diagnosis of optic neuritis could not be "confidently established" due to the sparse factual record. (Ex. A, p. 6; *see also* Ex. J, p. 1 (stating that "there is no evidence that petitioner had optic neuritis") (emphasis removed).) Dr. Bouffard was particularly concerned that petitioner was not examined close in time to the onset of his condition and that petitioner never underwent neuroimaging. (Ex. A, pp. 6, 9.) Given that petitioner was not examined close in time to onset of his condition, Dr. Bouffard concluded that "the expected course of optic neuritis could not be objectively confirmed." (*Id.* at 9.) Additionally, Dr. Bouffard expressed concern that petitioner did not undergo neuroimaging to rule out a compressive lesion, such as an aneurism, optic nerve sheath meningioma, or optic nerve glioma. (*Id.* at 7, 9.) He also stressed that petitioner's treaters did not record a detailed history for head trauma or initiate a work-up for syphilis. (*Id.*)

Dr. Bouffard further opined that petitioner's clinical presentation was inconsistent with optic neuritis. Significantly, Dr. Bouffard asserted that the nature of petitioner's eye pain did not fit with an optic neuritis diagnosis. (Ex. A, p. 7; Ex. J, pp. 1-2; Ex. L, p. 2.) Dr. Bouffard noted that "[p]atients with optic neuritis typically have several days of eye pain, exacerbated by eye movements, preceding or accompanying the onset of visual abnormalities." (Ex. A, p. 7.) Dr. Bouffard acknowledged that petitioner reported experiencing eye pain for about one day at the time of onset of his subjective dyschromatopsia or visual disturbances,[7] but stressed that petitioner continued to report frequent orbital pain thereafter. (*Id.*; *see also* Ex. J, pp. 1-2 (stressing that "[t]he pain of optic neuritis is transient and does not recur without another attack"); Ex. L, p. 1 (noting that the pain with optic neuritis usually lasts for less than a week). Specifically, Dr. Bouffard referenced petitioner's visit to Dr. Thurtell over a year after the onset of his condition during which he reported experiencing episodic eye pain three times a week. (Ex. J, pp. 1-2; Ex. L, p. 1.) He noted that relapse of optic neuritis would not occur as frequently as the episodes petitioner reported. (Ex. J, pp. 1-2.) Further, if petitioner were experiencing frequent attacks of optic neuritis, Dr. Bouffard opined that his examination at Dr. Thurtell's office would have shown abnormalities consistent with optic neuritis attacks. (*Id.* at 2.)

Additionally, Dr. Bouffard emphasized that petitioner was able to elicit or worsen his pain through palpation of the "brow" and the "nasal aspect of his nose," which is inconsistent with optic neuritis. (Ex. A, p. 7 (citing Ex. 1, p. 1); *see also* Ex. J, p. 1 (citing Ex. 1, p. 1) (reiterating that petitioner's pain associated with "pressing on soft tissue/bony structures around the orbit" is inconsistent with pain caused by optic nerve inflammation); Ex. L, p. 1 (stating that "[t]ouching the bones of the brow or nose in no way upsets the optic nerve and is obviously indicative of a source of pain other than optic neuritis") (emphasis removed).) Dr. Bouffard offered trochleitis, a supraorbital neuropathy, or posterior scleritis as more likely causes for the orbital eye pain petitioner described. (Ex. A, pp. 7, 9.) He also pointed out that petitioner reported sinus discomfort. (*Id.* at 7.)

Dr. Bouffard also opined that the appearance of petitioner's optic nerve did not comport with a diagnosis of optic neuritis. (Ex. A, p. 7.) While Dr. Bouffard acknowledged that petitioner had an increased cup to disc ratio in the left eye, he stressed that this is uncommon in optic neuritis. (*Id.* (citing William Stewart & Karen Reid, *Incidence of systemic and ocular disease that may mimic low-tension glaucoma,* 1(1) J. GLAUCOMA 27 (1992) (Ex. F-11); Jonathan Trobe et al., *Nonglaucomatous excavation of the optic disc,* 98 ARCH. OPHTHALMOL. 1046 (1980) (Ex. F-12); *see also*

[7] In a later report, Dr. Bouffard asserted that petitioner's orbital pain developed weeks after his visual disturbances initially occurred, while pain with optic neuritis typically precedes or accompanies the onset of vision loss. (Ex. L, p. 1 (citing Tr. 56).) This is inconsistent with Dr. Bouffard's earlier acknowledgement that petitioner experienced eye pain for about one day at the time of onset of vision complaints. (*See* Ex. A, p. 7.) However, Dr. Bouffard's later report followed the fact hearing, during which petitioner testified that he experienced color disturbances and blurry vision first, followed by orbital pain weeks later, which is inconsistent with his earlier reports to Dr. Larson and Dr. Thurtell. (Tr. 56; *see also* Ex. 1, p. 1; Ex. 3, p. 9.)

Ex. J, p. 2; Ex. L, p. 2.) Although increased cup to disc ratio is "an important feature to recognize in patients with optic neuropathy," such a finding is more suggestive of compressive lesions such as aneurysms, optic nerve sheath meningiomas, or tumors intrinsic to the optic nerve, as well as syphilis. (Ex. A, p. 7.) Dr. Bouffard noted that Dr. Thurtell suggested an orbital MRI with and without contrast, which would have been helpful to rule out an indolent compressive lesion, but petitioner declined. (*Id.*) He added that traumatic optic neuropathy is another source of cupped optic neuropathy but noted that petitioner's treaters did not record any notes regarding the presence or absence of head trauma. (*Id.*) Dr. Bouffard maintained that other than petitioner's increased cup to disc ratio, his optic nerve showed no abnormal findings. (Ex. L, p. 2.) Additionally, while Dr. Bouffard acknowledged that RNFL thinning suggests optic nerve damage, he explained that "it does not indicate any particular etiology." (Ex. A, p. 6.) Further, Dr. Bouffard stressed that petitioner's examinations showed no evidence of optic neuritis. Specifically, Dr. Bouffard noted petitioner's examinations revealed normal visual acuity and color vision, lack of RAPD, and normal visual fields. (Ex. J, p. 2 (citing Ex. 3, pp. 9-15).)

Regarding Dr. Thurtell's notation that petitioner's description of symptoms was consistent with Uhthoff's phenomenon, Dr. Bouffard stated that he "would be surprised to see [Uhthoff's] in the setting of anger" given that it is associated with body temperature. (Ex. A, p. 7.) Further, he opined that petitioner's episodes of visual disturbances triggered by cutting grass were more likely related to allergic eye symptoms or ocular surface disease.[8] (*Id.*) Regardless of whether petitioner's symptoms were consistent with Uhthoff's phenomenon, Dr. Bouffard stressed that Uhthoff's phenomenon is "not specific to demyelinating optic neuropathy and has been reported in other optic neuropathies." (*Id.* at 7-8.)

Finally, Dr. Bouffard asserted that "[t]he tempo of petitioner's vision loss is unusual for optic neuritis." (Ex. J, p. 1.; *see also* Ex. L, p. 1.) Dr. Bouffard noted that petitioner described monophasic vision loss with no improvement for seven months (Ex. J, p. 1 (citing Ex. 1, pp. 1-6).) Conversely, most patients with optic neuritis experience "subacute progressive vision loss for days to a few weeks, then slowly start to improve." (*Id.*) Dr. Bouffard therefore opined that petitioner's description of intermittent blurry vision is inconsistent with progressive inflammation of the optic nerve in patients with optic neuritis. (Ex. L, p. 1 (citing Tr. 10-12).) Thus, Dr. Bouffard concluded that petitioner's clinical presentation, his description of symptoms, and his ophthalmologic examinations do not support a diagnosis of optic neuritis.

[8] Dr. Bouffard elaborated that petitioner's complaints of episodic blurry vision "could easily have been accounted for by irritation of the cornea" and that petitioner is at higher risk of corneal irritation due to his history of smoking. (Ex. L, p. 2.) He explained that his suspicion of corneal irritation is further supported by petitioner's aggravation of symptoms while cutting grass and petitioner's use of Visine. (*Id.* (citing Ex. 44, pp. 2-3.)

ii. J. Lindsay Whitton, M.D., Ph.D.

Respondent also presented an expert opinion from immunologist Dr. Whitton. Dr. Whitton received his medical degree from the University of Glasgow in 1979 and his doctorate degree in virology also from the University of Glasgow in 1984. (Ex. C, pp. 1-2; Ex. D, p. 1.) Dr. Whitton has not sought licensure in the United States, nor has he practiced medicine in the United States. (Ex. C, pp. 2-3.) Dr. Whitton has served as a professor in the Department of Immunology and Microbiology at the Scripps Research Institute since 2008. (Ex. D, p. 2.) He has published extensively on the adaptive and innate immune response and on molecular mimicry. (*See id.* at 3-15.)

Like Dr. Steinman, Dr. Whitton dedicated most of his discussion to the mechanism for causation. (*See generally* Ex. C; Ex. H.) Dr. Whitton deferred to Dr. Bouffard's opinion on diagnosis and his expertise in neuro-ophthalmology. (Ex. C, pp. 3-4.) However, Dr. Whitton contended that Dr. Thurtell made only a "speculative diagnosis" of optic neuritis based on petitioner's description of events that occurred one year prior. (*Id.* (emphasis omitted).) Dr. Whitton emphasized Dr. Thurtell's language: "Based on the history, I suspect he had an attack of optic neuritis." (*Id.* at 3 (quoting Ex. 3, p. 14) (emphasis in original).) He maintained that "none of petitioner's physicians have ever identified any objective clinical signs of optic neuritis." (*Id.* at 4.)

IV. Standard of Adjudication

The parties dispute whether petitioner's symptoms were caused by optic neuritis. As a threshold matter, a petitioner must establish he suffers from the condition for which he seeks compensation. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Human Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). Accordingly, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record before applying the *Althen* test to determine causation." *Lombardi v. Sec'y of Health & Human Servs*., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 300aa-11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature,

causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination). Petitioner must prove by a preponderance of the evidence the factual circumstances surrounding his claim. § 300aa-13(a)(1)(A).

In general, contemporaneous medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1948) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992).

Nonetheless, treating physicians' opinions do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* § 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 Fed. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

Additionally, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (*quoting Murphy*, 23 Cl. Ct. at 733). When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

V. Discussion

As discussed in the procedural history above, there are two outstanding motions to strike that were filed during the briefing process. As a preliminary matter, it is necessary to resolve these motions to clarify the record upon which this fact finding will be made. This is accomplished in section (a) below. Section (b) then addresses the undersigned's finding of fact with regard to petitioner's diagnosis, concluding that there is not preponderant evidence supporting petitioner's preferred diagnosis.

a. Petitioner's Motion to Strike and Respondent's Cross-Motion to Strike

Petitioner moved to strike respondent's responsive brief on diagnosis and Dr. Bouffard's supplemental expert report filed as Exhibit M. (ECF No. 98.) Regarding respondent's responsive brief, although it was filed by the deadline on September 2, 2022, petitioner indicated that the parties "conferred in good faith and agreed upon filing the briefs at 1:30 p.m. EST." (*Id.* at 1.) Petitioner stated that while petitioner filed his brief at 1:33 p.m., respondent did not file his brief until 3:44 p.m. "and made no attempt to reach out to petitioner's counsel prior to the agreed upon deadline to request an extension/delay." (*Id.*) With respect to Dr. Bouffard's supplemental report, petitioner argued that it should be stricken because respondent never shared his intent to file the report and the action of filing such a report "lacks good faith." (*Id.*) Petitioner noted that "despite conferring with petitioner's counsel on both the extension of time for the filing of the briefs and the concurrent filing of [the responsive briefs], respondent's counsel never mentioned that [respondent was] seeking and/or planning to file an expert report." (*Id.* at 1-2.) He elaborated that "respondent has repeatedly attempted to add expert testimony to a factual issue." (*Id.* at 2.)

In his response to petitioner's motion to strike, respondent stressed that petitioner "relied extensively" on the Rebolleda et al. article, which was newly filed with petitioner's initial brief on diagnosis. (ECF No. 99, p. 1.) Respondent further noted that he moved for an extension of time to file his responsive brief on diagnosis on August 1, 2022, citing the need for additional time to allow for "feedback from his expert as to the new literature petitioner filed with his initial brief." (*Id.* (quoting ECF No. 94.) Respondent asserted that Dr. Bouffard's supplemental report responds specifically to the comments regarding optic neuritis contained in petitioner's initial brief and the Rebolleda et al. article. (*Id*.) Respondent argued that petitioner's motion to strike "is effectively a motion to exclude." (*Id.* at 2.) He maintained that his "actions were prompted by petitioner's untimely evidence" and noted that petitioner did not explain why the Rebolleda et al. article was not provided before briefing. (*Id.*) In the event the court finds it necessary to strike respondent's brief and supplemental expert report, respondent cross-moved to strike the Rebolleda et al. article as an untimely disclosure. (*Id.* at 4.)

In his reply, petitioner stressed that respondent did not put petitioner on notice that an expert report was forthcoming. (ECF No. 100, p. 1.) He argued that conferring with an expert prior to filing a brief is a customary practice and does not indicate that the expert intended to prepare an additional report. (*Id.*) Petitioner cited the scheduling order issued on March 1, 2022, which indicated that "the factual record [was] sufficiently developed to fairly resolve the issue of diagnosis." (*Id.* at 2 (citing ECF No. 88, p. 1).) Petitioner disputed respondent's contention that he relied extensively on the Rebolleda et al. article, noting that his initial brief mentioned the article only once. (*Id.* (citing ECF No. 93, p. 8.) Petitioner also claimed that the majority of Dr. Bouffard's supplemental report does not address the Rebolleda et al. article, but instead discusses other aspects of petitioner's initial brief. (*Id.*) Petitioner further noted that respondent's responsive brief discusses Dr. Bouffard's supplemental report extensively. (*Id.* at 3.)

Following the fact hearing on March 30, 2021, respondent was afforded the opportunity to submit an additional supplemental report from Dr. Bouffard. (ECF No. 86; Ex. L.) As noted by petitioner, during a status conference held on March 1, 2022, I then later indicated that "the factual record has now been sufficiently developed to fairly resolve the issue of diagnosis." (ECF No. 88, p. 1.) Based on the discussion during the status conference and the notion that the record was ripe for a ruling on diagnosis, further evidence was not anticipated. (*See* ECF Nos. 88, 89.) Although petitioner filed the Rebolleda et al. medical article concurrent with his initial brief, the article was not interpreted by an expert. Additionally, contrary to respondent's assertion, petitioner did not rely heavily on the article in his brief. Instead, he cited it only once throughout the ten-page brief. (ECF No. 93, p. 8.) Thus, the filing of the Rebolleda et al. article, even if fairly subject to objection, did not reasonably open the door to the filing of an additional report from Dr. Bouffard. Thus, that aspect of petitioner's motion seeking to strike Dr. Bouffard's supplemental expert report is granted.

However, given the analysis below, there is clearly no prejudice to respondent in accepting into evidence the Rebolleda et al. article. Vaccine Rule 8(b)(1) ("In receiving

evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.") Thus, and respondent's cross-motion is denied.

Finally, petitioner is unpersuasive in further arguing that respondent's brief should also be struck. The undersigned's scheduling order only required that the simultaneous briefs be filed on the same date and petitioner is not persuasive in suggesting the two-hour difference in filing times is significant. To the extent respondent's brief does discuss Dr. Bouffard's now struck report, most such references include alternative citations finding support elsewhere in the record. Those that do not are easily disregarded and, in any event, respondent's argumentation does not in itself constitute evidence.

Accordingly, petitioner's motion to strike is **GRANTED in part and DENIED in part**, and respondent's cross-motion to strike is **DENIED**.

b. Finding of Fact as to Diagnosis

Petitioner has not preponderantly established that he suffered optic neuritis. Dr. Bouffard persuasively explained that petitioner's clinical presentation is inconsistent with optic neuritis and it is unlikely that petitioner's reported eye pain was caused by that condition. While optic neuritis patients typically experience transient pain before or accompanying vision loss, petitioner described ongoing orbital pain for several months following his initial visual disturbance. (*See* Ex. A, p. 7 (citing Ex. 1, p. 1); Ex. J, pp. 1-2; Ex. L, p. 1 (citing Tr. 19-20, 56).) Petitioner's ability to elicit or worsen his orbital pain through palpation of his brow and nose is also inconsistent with pain associated with optic neuritis. (Ex. A, p. 7 (citing Ex. 1, p. 1); Ex J, p. 1.) Additionally, petitioner's description of ongoing vision loss with no improvement for several months is atypical for optic neuritis. (Ex. J, p. 1 (citing Ex. 1, pp. 1-6); Ex. L, p. 1.) Further, petitioner's episodic blurry vision is inconsistent with progressive inflammation of the optic nerve seen in patients with optic neuritis. (Ex. L, p. 1 (citing Tr. 10-12).) Although Dr. Thurtell noted that petitioner's description of symptoms was consistent with Uhthoff's phenomenon, Dr. Bouffard stressed that Uthoff's phenomenon is not specific to optic neuritis. (Ex. A, pp. 7-8.) Thus, petitioner's medical history and treatment course suggest that his symptoms were not caused by optic neuritis.

Furthermore, objective examinations and testing did not reveal evidence for optic neuritis. Dr. Bouffard opined that the appearance of petitioner's optic nerve did not suggest optic neuritis. (Ex. A, p. 7.) Although petitioner had an increased cup to disc ratio in his left eye, Dr. Bouffard explained that this abnormality is uncommon among patients with optic neuritis. (*Id.* (citing Steward & Reid, *supra,* at Ex. F-11; Trobe et al., *supra,* at Ex. F-12); Ex. J, p. 2; Ex. L, p. 2.) Dr. Bouffard acknowledged that an increased cup to disc ratio indicates optic neuropathy but noted that it likely reflects compressive lesions such as aneurysms, optic nerve sheath meningiomas, or tumors intrinsic to the optic nerve, or syphilis. (Ex. A, p. 7.) While petitioner's RNFL thinning

suggests optic nerve damage, Dr. Bouffard explained that "it does not indicate any particular etiology." (*Id.* at 6.)

Concurrent with his initial brief, petitioner offered the Rebolleda et al. article to dispute Dr. Bouffard's contention that an increased cup-to-disc ratio is uncommon in optic neuritis. (ECF No. 93, p. 8 (citing Rebolleda et al., *supra*, at Ex. 47.) However, petitioner misinterprets Dr. Bouffard's opinion. Dr. Bouffard did not assert that cup-to-disc asymmetry is *never* observed in optic neuritis as petitioner suggests. He opined that it is not specific to optic neuritis and *uncommon* as a result of optic neuritis. (Ex. A, p. 7; Ex. J, p. 2; Ex. L, p. 2.) Consistent with Dr. Bouffard's observation, the Rebolleda article begins by acknowledging "[e]ven though optic disc cupping is usually identified with glaucoma, it may be seen in other, less common optic nerve diseases[.]" (Rebolleda et al., *supra*, at Ex. 47, p. 890.) The article further states while cup asymmetry has been observed in patients with optic neuritis, "the most common change in the optic nerve head (ONH) after optic neuritis is optic disc pallor[.]" (*Id.*) The article qualified its observations by citing another study that found no significant increase in optic disc cupping among patients with optic neuritis. (*Id.*) Ultimately, the authors characterize the study as a first of its kind demonstration that supports inclusion of optic neuritis as one among many diseases that can cause optic disc cupping. (*Id*. at 894.) On the whole, the article does not provide evidence contrary to Dr. Bouffard's opinion that the appearance of petitioner's optic nerve was not necessarily suggestive of optic neuritis.

Moreover, Dr. Bouffard stressed that petitioner's ophthalmologic examinations revealed normal visual acuity and color vision, lack of RAPD, and normal visual fields. (Ex. J, p. 2 (citing Ex. 3, pp. 9-15.) In fact, Dr. Larson described petitioner's visual acuity as "excellent," and petitioner measured 20/20 in both eyes during Dr. Thurtell's visual examination. (Ex. 1, pp. 1-2; Ex. 3, pp. 11, 14.) Further, petitioner correctly identified all color plates in the Ishihara color test both at Dr. Larson's office and at Dr. Thurtell's office. (Ex. 1, p. 2; Ex. 3, pp. 11, 14.) Thus, based on petitioner's ophthalmologic examinations, the evidence preponderates against a finding that petitioner suffered optic neuritis.

Dr. Lefkowitz only briefly discussed the diagnosis dispute in his report responding to Dr. Bouffard. (Ex. 40.) He merely concluded that petitioner did not suffer from ischemic, post-inflammatory, glaucomatous, or toxic etiologies without providing any explanation other than that petitioner's visual testing did not indicate glaucoma. (*Id.* at 3.) Dr. Lefkowitz asserted that petitioner suffered from optic neuritis without offering any discussion or rebuttal regarding Dr. Bouffard's specific critiques about petitioner's presentation being inconsistent with optic neuritis. (*See id.*) In any event, Dr. Bouffard's opinion is also entitled to more weight given his specialization in neuro-ophthalmology. Dr. Lefkowitz did not discuss any experience in neuro-ophthalmology. (*See* Exs. 40, 41.) In contrast, Dr. Bouffard is board-certified in neurology, completed a neuro-ophthalmology fellowship at the Massachusetts Eye and Ear Infirmary, and has written multiple peer-reviewed publications in the field of neuro-ophthalmology. (Ex. A, pp. 2-3; Ex. B, pp. 2-3.) Given Dr. Bouffard's experience and additional qualification in

neuro-ophthalmology, his opinion regarding petitioner's clinical presentation and testing is deserving of greater weight than that of Dr. Lefkowitz.

Petitioner otherwise relies on Dr. Thurtell's notation as treating physician that he "suspect[ed] [petitioner] had an attack of optic neuritis." (Ex. 3, p. 14.) However, although Dr. Thurtell is a treating physician, his optic neuritis diagnosis does not outweigh Dr. Bouffard's far more detailed opinion that petitioner's presentation and objective examinations were inconsistent with optic neuritis. The quality of Dr. Thurtell's diagnosis suffers given that it was made over one year after the onset of petitioner's symptoms. The Court of Federal Claims has explained that the added weight often afforded treating physician opinions is due at least in part to their ability to observe the unfolding of the condition at issue. *Nuttall v. Sec'y of Health & Human Servs*., 122 Fed. Cl. 821, 832-33 (2015) (explaining that the Federal Circuit "found that a treating physician who was familiar with the patient both before and after the alleged vaccine injury is likely to be in a better position than an expert retained after the fact" to opine with respect to vaccine causation), *aff'd* 640 Fed. Appx. 996 (Mem.) (Fed. Cir. 2016). Here, as noted by Dr. Bouffard, without an examination close in time to the onset of symptoms, "the expected course of optic neuritis could not be objectively confirmed." (Ex. A, p. 9.)

Instead, Dr. Thurtell expressed that he suspected an optic neuritis attack "[b]ased on the history" rather than specifically citing objective findings. (Ex. 3, p. 14.) In fact, he noted that his neuro-ophthalmic evaluation supported only mild optic neuropathy. (*Id*.) However, the history petitioner provided to Dr. Thurtell was inconsistent with the history he provided to Dr. Larson several months earlier. (*Compare* Ex. 1, p. 1 (reporting vision loss over the course of one month to Dr. Larson), *with* Ex. 3, p. 9 (describing progressive vision loss over the course of "days"). Further, Dr. Bouffard noted that Dr. Thurtell did not record a detailed history for head trauma or call for a work-up to rule out other causes for petitioner's symptoms. (Ex. A, pp. 7, 9.) Finally, petitioner declined the neuroimaging Dr. Thurtell recommended to help confirm the cause of petitioner's symptoms. (*Id.*) Therefore, Dr. Thurtell's diagnostic opinion based on the history provided by petitioner cannot overcome the dearth of objective findings or testing to support the optic neuritis diagnosis. *See Davis v. Sec'y of Health & Human Servs.*, 20 Cl. Ct. 168, 173 (1990) (stating that a treating physician's conclusions "are only as good as the reasons and evidence that support them").

Accordingly, for the reasons discussed above, petitioner has not preponderately established that he suffered optic neuritis.

VI. Conclusion

In light of the above, the evidence preponderates against a finding that petitioner suffered optic neuritis. However, petitioner specifically pled optic neuritis in his petition. (ECF No. 1.) Moreover, Dr. Steinman's causal opinion is based on optic neuritis. (*See*, *e.g.*, Ex. 8, p. 7.) Accordingly, this fact finding is fatal to petitioner's case as it is currently framed.

A separate scheduling order will issue giving petitioner an opportunity to indicate whether he intends to file an amended petition and supplemental expert report based on an injury other than optic neuritis. However, if petitioner concludes that he cannot reasonably file an amended petition or expert report, I will issue a decision dismissing the case based on the existing record.

Given the rulings in section V.a granting in part and denying in part petitioner's motion to strike and denying respondent's cross-motion to strike, the Clerk's Office is directed to strike the filings contained in ECF No. 96 from the record.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master